

Remarks

Applicant believes that this response places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this response, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Initially, Applicant wishes to thank the Examiner for responding to Applicant's arguments in a previous response to an Office Action. Claims 1-43 were originally presented in the subject application. Claims 29-43 were withdrawn in a previous response to an Office Action. Claims 1-28 remain in this case. The Examiner's concerns are addressed separately below in the order raised in the outstanding Office Action. No new matter has been added.

Rejections under 35 U.S.C. §102(b)

Claims 1, 2, 8, 9, 15, 16, and 23-28 stand rejected under § 102(b) as anticipated by Howard, III, U.S. Patent No. 5,945,341 (Howard '341). Applicant respectfully traverses this rejection.

1. Detection of misidentification of the test strip.

Howard '341 does not anticipate the claimed characteristic of using the sample analysis pads ("test pads") and fields ("test fields") to detect misidentification of a test strip.

a) The claims distinguish marker fields used for strip identification, from sample analysis test pads and fields

Independent claims 1, 8, and 15, from which the remaining claims rejected under this section depend, distinguish the marker fields, used for identification, from the test pads and test fields, which are used for analysis of the sample and for misidentification determination.

Claims 1 and 8 recite "a diagnostic test strip . . . having a plurality of test pads separate from said marker fields, said test pads having reagents thereon." Claim 15 makes a similar distinction. Claim 15 recites "a test strip having a plurality of tests fields

on its surface ... and at least two distinct marker fields on the same surface of said test strip as said test fields." The marker fields relate to the identification of the test strip, as recited in claim 15: "said marker fields reflecting light at different ranges of wavelengths from each other... in a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip." In contrast, the claim 15 test fields are for analysis of the sample, as defined in the specification. (See, e.g., Application at p.7 lines 18-24). Therefore, the test pads / fields in the independent claims are separate and distinct from the marker fields.

b) The claimed test pads / fields are configured to detect misidentification of the test strip.

In the claimed invention, the misidentification step is implemented not with the marker fields used to identify the strip, but rather, with the same test pads that are used to analyze the sample. Claims 1 and 8 specify that the misidentification is accomplished using the test pads, rather than by using a separate control or identification area. In particular, claim 1 recites "determining that the test strip is misidentified in the event said infrared reflectance of one or more of the plurality of test pads is outside of the acceptable predetermined range." Claim 8 similarly recites "reading the infrared reflectances from each of the plurality of test pads; ... and determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range."

Claim 15 also specifies that the misidentification feature is implemented through the test fields for the sample, rather than through the separate marker fields. Claim 15 recites "f) determining that said test strip is misidentified in the event said infrared reflectances from said test fields are outside of the predetermined range."

c) Howard '341 does not detect misidentification using sample analysis pads

Unlike the claimed invention, Howard '341 does not determine whether the test strip has been misidentified, and does not do so using the sample analysis test fields. Howard '341 discloses "one test control region 502 FIG. 2 and one test region 501."

(Howard '341 col. 8 lines 47-48). The Howard '341 test region 501 is used to analyze a sample, and is not taught as being used to detect a misidentification of the strip.

After the color sequence has been identified [using the marker fields], the instrument will move the test strip 22 to the proper location, i.e. test field 501 and collect data at the proper wavelengths and at the proper time or times such that the collected data can be analyzed by an appropriate algorithm to complete the assay. These data are collected by illuminating the test field 501 with white light from the light source and determining the amount of reflectance from the test field based on the detection of light received from the illuminated portion of the strip 501 at an angle (e.g. 45 degrees) from the upper surface of the strip 22.

(Howard '341 col. 6 lines 51-61). Control stripe 502, on the other hand, is used to determine whether sufficient quantities of sample are on the strip. Howard '341 describes "stripe 502 ... [as] a control stripe that changes color if sufficient sample volume is detected." (Howard '341 col. 3 lines 57-58).

The Office has stated that Howard '341 does in fact determine whether a strip has been misidentified, based on the infrared reflectances of the reagent fields, citing the "errors" discussed by Howard '341 at col. 8 lines 49- col. 9 line 7. (Office action, p. 12). However, Applicant respectfully submits that these "errors" do not refer to misidentification, but rather, to procedural methods.

The instrument... will position the test control region 502... under read head 34... and measure the diffuse reflectance in the infrared (IR), red, green, and blue spectral regions. ... The analysis of the test control region will indicate *whether or not the proper procedural methods were followed*. For example, the reflectance in the red may be computed and then compared with a table of reflectance ranges *to determine if the proper procedural methods were followed*. Analysis of the test control region will either allow the test results to be analyzed or result in *an error message on display 16 FIG. 1 indicating that the proper procedural methods were not followed*. ... If there was no error, the analysis results may be reported on printer 32 FIG. 1.

(Howard '341 col. 8 lines 49-52, 55-63; col. 9 lines 7-8) (emphasis added).

The "error" referenced in the foregoing passage thus refers to improper procedural methods as determined by the analysis of the test control region 502. Moreover, it is clear that this analysis of control region 502 can have only one of two possible outcomes, namely, either an error message is sent to display 16, or alternatively, the absence of any

errors will “allow the test results to be analyzed”. Since, at this point, the control region 502 has already been analyzed, it is clear that these “test results to be analyzed” are those obtained from test region 501. It follows then that it is these test region 501 results that are “reported on printer 32”, and that they will be reported only if the earlier analysis of control region 502 indicated no procedural errors. Accordingly, it is evident that the cited passage, including the “error” discussed therein, refers to procedural errors and not to detecting misidentification of a test strip.

This conclusion is further supported by subsequent language in Howard ‘341, which describes another, simplified approach for using control region 502 to detect procedural errors.

In another preferred embodiment, there is also a control region 502 will generate a specific color if the proper procedures for the test [are] followed by the user. More particularly, if the test strip were not exposed to sufficient sample, this procedural fault will be detected.

(Howard ‘341, col. 9, lines 9-13).

This alternate embodiment ostensibly simplifies procedural fault detection analysis by enabling the instrument to look for only one single “specific” color, rather than the plurality of colors (IR, red, green and blue) as in the embodiment discussed above.

The Office Action also states that Howard ‘341 inherently discloses detecting misidentification of the test strip. Specifically, the Office states that “[i]n this cited disclosure, it appears that the infrared reflectances of the test region (501, fig. 2) are measured to determine, i.e. whether an error occurred. This ‘error’ inherently refers to a misidentification of the test strip since Howard ‘341 specifically teaches in col. 1, lines 6-8 that his invention is concerned with the method of optical identification of test strips.” (Office Action p.12).

Applicant respectfully submits that as discussed above, the cited “error” is generated as a result of an analysis of the control region 502, not as a result of an analysis of test region 501. Moreover, the cited “error” does not correlate to misidentification, but rather, as also discussed, is correlated to improper procedures. Further still, while Howard ‘341 does indeed discuss the identification of test strips, such identification does not necessarily correlate to the separate step of misidentification. Howard ‘341 also

discloses identification solely by use of marker fields, and makes no suggestion that once the marker fields have been used to identify a strip, the test field is used in a subsequent step to detect a misidentification.

According to the MPEP, a reference does not inherently disclose a characteristic unless the characteristic *necessarily* follows from the disclosure. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP §2112(IV). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP §2112(IV). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112(IV).

The fact that Howard '341 generally involves identification of a test strip, does not necessarily mean that the term "error" refers to either an analysis of test field 501, or that such an analysis represents the misidentification of a test strip. Instead, as discussed above, the context of the term "error" in the cited passage strongly, if not explicitly, suggests that the term refers solely to a failure to follow proper procedures, based on an analysis of control region 502 (not test field 501).

Moreover, the fact that Howard '341 explicitly discloses another, substantially distinct approach for determining his identification, i.e., by using the marker fields, militates against a finding that identification is necessarily provided by other means. (See, e.g., H '341 claim 1, which states that: "marker fields reflect light... in a coded sequence of ranges of wavelengths which coded sequence correlates to information concerning identification of the test strip".) Therefore, Applicant respectfully submits that Howard '341 does not inherently disclose use of test fields to detect the misidentification of a test strip.

Since Howard '341 does not explicitly or inherently disclose misidentification of a test strip using its test fields, Howard '341 could not have anticipated the claimed invention.

Rejections under 35 U.S.C. §102(e)

Corey et al., U.S. Patent No. 6,316,264

Claims 1-3, 5, 7-10, 12, and 14 stand rejected under § 102(e) as anticipated by Corey et al., U.S. Patent No. 6,316,264. Applicant respectfully traverses this rejection.

The independent claims disclose a determination of whether the test strip has been misidentified. As discussed above, claim 1 recites "determining that the test strip is misidentified in the event said infrared reflectance of one or more of the plurality of test pads is outside of the acceptable predetermined range;" and claim 8 similarly recites "reading the infrared reflectances from each of the plurality of test pads; ... and determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range."

In contrast, Corey et al. do not disclose determining if a strip has been misidentified, based on whether infrared reflectances of sample analysis test areas are within an acceptable predetermined range. Corey et al. instead focus on the problem of misalignment of a test strip, stating that "the infrared dye ensures that the test strips are properly aligned in an apparatus that detects and measures the test pad response," and that "[t]he present invention is directed to a dry phase test strip that ensures proper alignment of the test strip in a detection apparatus." (Corey et al. col. 1 lines 15-18; col. 3 lines 61-63).

The Office Action cites several passages to support its position that Corey teaches determining misidentification of a test strip. However, it is respectfully submitted that these passages refer to detection of misalignment, rather than misidentification, of the strip. (See, e.g., Corey et al. col. 3, lines 41-54, which describes the mispositioning of a test strip). Since Corey et al. do not teach detection of misidentification of a test strip, Corey et al. do not explicitly anticipate the instant claims.

The Office also appears to have concluded that Corey inherently discloses identifying a test strip by reading IR reflectances. "Based on the disclosure of Corey, it

appears that Corey 'identifies' the test strip by reading reflectances because the detection apparatus must detect or identify the IR dye for the test strip to determine, i.e. the test strip's alignment properties." (Office Action p.13).

However, Applicant respectfully submits that merely detecting the presence of an IR dye is not the same thing as identifying an underlying test strip. Merely correlating the location of an IR dye to the location (alignment) of an underlying device does not constitute an inherent disclosure of detecting either the identification, or more relevantly, the misidentification, of the device. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." MPEP § 2112 (IV).

In order for Corey to inherently disclose identifying a test strip by reading reflectances of one or more of a plurality of marker fields as suggested, such an identification must necessarily follow from using infrared reflectances to detect misalignment of the test strip. Identification of a strip does not necessarily follow from determining whether the strip is misaligned, since the mere presence and/or physical orientation (e.g., alignment) of a device may be determined without identifying the device in question. Moreover, even assuming for the sake of argument that Corey did inherently identify a test strip, e.g., by capturing reflectances from marker fields, such identification does not necessarily constitute determining the misidentification of the strip by capturing reflectances from test fields. Indeed, as claimed, these are two separate and distinct steps. Therefore, the cited portions of Corey et al. do not disclose using infrared reflectances from test fields/pads to detect misidentification of the test strip as claimed.

The Office Action also states that "Corey teaches the step of determining whether a test strip is misidentified in, for example, column 14, lines 8-20. In this cited disclosure, Corey teaches colored test strips that were determined to be misidentified (i.e. false positive or false negative test assays) based on the infrared reflectance of the reagent areas." (Office Action p.13).

The cited passage from Corey is as follows.

To demonstrate the effect of a visible dye, the above four different color tapes, i.e., red, green, blue, and black, were laminated to different plastic handles, and then all ten reagent pads present on a MULTISTIX® 10 SG test strip were laminated onto the handles. The results, for both negative and positive test solutions for these colored tape strips, were compared to control strips mounted on an extra thick handle to equal the tape strip thickness. With all reagents used on a MULTISTIX® test strip, some or all of the colored tapes caused either false positive or false negative test assays. These results (Table 3) show that a visibly colorless dye, i.e., an IR dye, must be used as the marker to ensure proper alignment of a test step in a spectrophotometer.

This paragraph describes an experiment to show that "a visibly colorless dye, i.e., an IR dye," is better than a visible color dye. The IR dye is used as a marker for alignment, not for identification (or for misidentification). Therefore, Corey et al. do not disclose using infrared reflectances to detect misidentification of a test strip.

In summary, the cited references do not disclose each of the characteristics of the claims, and therefore do not anticipate the claims.

Rejections under 35 U.S.C. §103(a):

Claims 4, 6, 11, 13, and 18-22

Claims 4, 6, 11, 13, and 18-22 stand rejected under 103(a) as unpatentable over Howard '341. Applicant respectfully traverses this rejection.

As discussed above, the claims include the element of determining whether a test strip has been misidentified by use of the sample analysis test pads. In contrast, the Howard '341 sample analysis test fields ("test region 501") are not used to detect misidentification of the strip, as discussed above in relation to the § 102(b) rejections. (Howard '341 col. 3 lines 57-58; col. 6 lines 51-61; col. 8 lines 47-48).

The Board of Patent Appeals and Interferences has recently specified that an obviousness finding requires an "apparent reason" to combine (or modify) the references.

The KSR Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some 'apparent reason to combine the known elements in the fashion claimed.'

In re Whalen, Appeal 2007-4423 for Application 10/281,142, p.16 (BPAI 2008) (precedential opinion). Howard '341 teaches using the marker fields for identification, as discussed above. There is no apparent reason to modify Howard '341 to add the feature of using the sample analysis test fields for misidentification detection, particularly after the aforementioned identification using marker fields has already been accomplished. Therefore, Howard '341 does not render the claims obvious.

Claims 15-17, 23-25, and 28

Claims 15-17, 23-25, and 28 stand rejected under § 103 as unpatentable over Howard et al., U.S. Patent 5,654,803 ("Howard '803"), in view of Howard '341. This rejection is respectfully traversed. Claim 15, from which claims 16, 17, 23-25, and 28 depend, recites identifying the strip through the sample analysis test fields (as opposed to the separate marker fields).

The Office Action states that "Howard '803 does not specifically teach the step of determining if a test strip is misidentified", but that it "would have been obvious to modify Howard '803 in view of Howard '341 because it would be desirable to have a method of determining whether a test strip is misidentified to insure the test results

produced from a test strip are accurate." (Office Action p.11-12). Applicant respectfully submits that for the reasons discussed above, it would not have been obvious to add a misidentification determination step after an identification step had already been successfully completed. Moreover, even assuming for the sake of argument that determining misidentification after a successful identification were in fact obvious, it would not have been obvious to determine misidentification using the *test analysis fields*. Instead, the more likely approach would have been to use the marker, or identification fields in a subsequent verification/misidentification step.

Under the obviousness test set out in *In re Whalen*, there must be an apparent reason to make the proposed modification. *In re Whalen*, Appeal 2007-4423 for Application 10/281,142, p.16 (BPAI 2008). For the reasons stated above, there would have been no apparent reason to either add a discrete misidentification detection feature, or to do so using test analysis fields instead of identification marker fields. Therefore, the cited references do not render the invention obvious.

CONCLUSION

For at least each of the foregoing alternate reasons, Applicant respectfully requests reconsideration and allowance of the pending claims. The dependent claims are believed to be allowable for the same reasons as the independent claims from which they depend, as well as for their own additional limitations. Applicant therefore further submits that all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing

Docket No. MSE #2620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Sampson', followed by a horizontal line.

Richard L. Sampson
Attorney for Applicant
Registration No. 37,231

Dated: March 2, 2009
SAMPSON & ASSOCIATES, P.C.
50 Congress Street
Suite 519
Boston, MA 02109
Telephone: (617) 557-2900
Facsimile: (617) 557-0077